

REMARKS

Applicant intends this response to be a complete response to the Examiner's **12 August 2003** Non-Final Office Action. Applicant has labeled the paragraphs in his response to correspond to the paragraph labeling in the Office Action for the convenience of the Examiner.

Election/Restriction

The Examiner contends as follows:

Applicant's election with traverse of Group II, claims 23-34, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the same search is required for the inventions of Groups I and II. This is not found persuasive because the search for each of the inventions of Groups I and II is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine the two inventions in one application.

The requirement is still deemed made FINAL.

Applicants acknowledge the finality of the Election, but are still disappointed that the method claims cannot be simultaneously examined with the composition claims.

Claim Rejections - 35 U.S.C. § 112

Claims 23-34 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of controlling fire ants using a composition comprising an effective amount of the demonstrated strain of *Rhodobacter capsulatus* in a viable (i.e., not dead) state, does not reasonably provide enablement for "controlling any and all insect populations using a composition comprising any and all species and subspecies of *Rhodobacter* (dead or alive) as instantly claimed (nor for using an extract thereof or a composition which includes at least one endotoxin produced thereby). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention commensurate in scope with these claims.

The Examiner contends as follows:

With respect to the elected invention, Applicants have reasonably demonstrated that a composition comprising an effective amount of a particular strain of *Rhodobacter capsulatus* in a viable (i.e., not dead) state has insecticidal activity against fire ants. As noted in parent Application No. 09/951,833, the state of the art recognizes that particular gram-negative bacterial strains - i. e., a particular ATCC strain of *Serratia marcescens* (ATCC - 17999, previously known as *Serratia piscatorum*) and a particular strain of *Enterobacter cloacae* (ATCC 15337, previously known as *Aerobacter aerogenes*) have insecticidal activity, as do genetically altered gram-negative bacteria, especially those containing one or more

Bacillus thuringiensis (*Bt*) toxin genes (see, e.g., art rejections of record set forth in parent Application 09/1951,833) - each of which is in a viable (not dead) state. However, the claims broadly encompass a method of controlling any and all insect populations using a composition comprising any and all species and subspecies strains of the gram-negative bacterial genus *Rhodobacter* in a live or dead state, or an extract thereof, which is clearly beyond the scope of the instant disclosure. Since the vast majority of prior art microbial insecticidal compositions, including those against ants such as fire ants, are comprised of viable fungi or viable gram-positive bacteria (e.g., *Bt*) or, alternatively, comprised of genetically altered viable gram-negative bacteria (e.g., one which contains *Bt* genes), those skilled in the art are unlikely to accept the data as being correlatable to the broadly claimed insecticidal method which encompasses the use of any and all species and subspecies strains of *Rhodobacter* instantly claimed (e.g., non-genetically altered strains, as well as those that are dead). Further regarding instant claim 28, *Rhodobacter* bacteria are not recognized in the art as being capable of producing an endotoxin. Accordingly, without clear and convincing evidence to the contrary, the claimed composition comprising an endotoxin (or an extract including an extract containing such an endotoxin) produced by the claimed *Rhodobacter* (as recited in instant claim 28) is not deemed enabled.

Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using a composition for controlling fire ants comprising an effective amount of the particular demonstrated *Rhodobacter capsulatus* strain in a viable (i.e., not dead) state, as shown in instant Examples 6 and 7 (however, please note that new matter cannot be introduced into file instant specification in response to this Office action).

With respect to the elected invention, claims 23-34 are also rejected under U.S.C. § 112, first paragraph, because the claimed invention is not deemed enabled without **complete evidence either that the claimed biological material (i.e., the particular demonstrated *Rhodobacter capsulatus* strain shown in instant Examples 6 and 7) is known and readily available to the public or complete evidence of the deposit of the biological material.**

It is apparent that the demonstrated microorganism is required to practice the elected claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement 112, first paragraph, may be satisfied by a deposit of the microorganisms. See 37 C.F.R. § 1.802.

The specification ages the demonstrated microorganism and it is not apparent if the microorganisms are readily available to the public. The specification must contain the date that the microorganism was deposited, the name of the microorganism and the address of where the microorganism were deposited.

If the deposit has been made under the terms of the Budapest Treaty, then an affidavit declaration by Applicants or someone associated with the patent owner who is in position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number; stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the

depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 808.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 C.R. § 80 1-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer,

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1,809(d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

Applicants disagrees with the Examiner's attempt to limit the scope of the application to a particular species of *Rhotobacter*, because all of the species within the *Rhotobacter* genus have sufficient similarity that the cellular components that induce death in fire ants will remain the same. Applicants have now shown that at least four different gram-negative bacteria from significantly different genres are capable of controlling insect populations. Thus, the information well supports the contention that something in a gram-negative bacterial, when ingested by insects such as imported fire ants, invokes a lethal response. Although the original bacteria came from a specific source, no evidence has been supplied or cited by the Examiner that is contrary to a broad pronouncement that the insect population control attributes of these representative as genus and family are not shared by all bacteria from the family – gram negative bacteria. Moreover, Applicants did not take special steps in finding a specific *Rhotobacter* to test. And as is apparent from the test results, the selected gram-negative bacteria was also effective against fire ants. Furthermore, the bacteria are effective both as viable bacteria and as dead bacteria – see paragraph 107 at page 25, line 1. Thus, the specification does indeed support viable and non-viable bacteria, and, because non-viable bacteria are effective in insect population control, then so to will be extracts for the bacteria.

Although Applicants fully believe that the specification is sufficiently broad to support all species of the genus *Rhodobacter*, Applicants have decided to focus on the specific species of *Rhodobacter* for this application and will pursue broader claims at a later date.

Applicants *Rhodobacter* species is available commercially from BioStim, licensee of the technology, that will submit a viable culture to a depository if allowable subject material matures from this application.

Claims 23-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner contends as follows:

Claim 23 is rendered vague and indefinite by the phrase "at least one Gram negative bacteria" (lines 1-2). It is unclear by this phrase if the composition actually contains only one gram negative bacterium from the recited genus or if it contains (an effective amount of?) one species of gram-negative bacteria from the recited genus.

Claims 28 (line 1) and 33:(line 2) recites the limitation "the extract". There is insufficient antecedent basis for this limitation in these claims.

Claim 33 recites the limitation "the effective amount" in line 1. There is insufficient antecedent basis for this limitation.

Claim 34 recites the limitation "the insect " (is this meant to define the insect population?) and "the effective amount" in line 1. There is insufficient antecedent basis for these limitations in the claim.

Claim 34 also recites the limitation "mound" in line 2. There is insufficient antecedent basis for this limitation in the claim (e.g., what mound?).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Applicants have canceled pending claims 23-34 and proposed new claims 35-59, which Applicants believe remove all the above identified 112, 2nd paragraph problems.

Claim Rejections - 35 U.S.C. § 102

Claims 23-26 and 28-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jong et al (KR 9411524 - DWPI Abstract), with evidence provided by the ATCC Catalogue of Bacteria and Bacteriophages (18th ed., 1992).

The Examiner contends as follows:

A composition comprising a *Rhodobacter* such as *Rhodobacter capsulatus* and an insect food, such as a carbohydrate or cellulosic material, is claimed.

Jong et al teach a composition comprising *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized

in the art as *Rhodobacter* i.e., *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*, however, *Rhodopseudomonas capsulatus* has been renamed *Rhodobacter capsulatus* - see, e.g., page 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*) as an active ingredient therein, whereby the composition further includes carbohydrate and/or humus (please note that humus is dead plant material and, thus, would inherently contain cellulosic material therein since cellulosic material such as cellulose is "amorphous carbohydrate polymer (C₆H₁₀O₅), the main constituent of all plant tissues and fibers" (Webster's Dictionary, 1988) -- see DWPI Abstract. Based upon the unclarity of claims 33-34 (including the lack of antecedent basis limitations discussed above), the composition taught by Jong et al. reads upon these claims, as drafted. Please note that nothing would preclude the additional ingredient(s) disclosed by the cited reference from being used as "insect food."

Therefore, the reference is deemed to anticipate the instant claims above.

Applicants disagrees that Jong et al anticipate the present invention or renders the present invention obvious. Jong et al treats bad smell. The Jong et al composition includes 1-8 wt.% of the microbe and **below** 1 wt.% of lower carbohydrate as culture agent. Thus, the carbohydrate is part of the culture medium used to grow the bacteria and is only an incidental part of the composition. The bacterial composition of Jong et al is used as fed supplement for animals (mixed with animal feed) and acts to reduce bad smells produced by the animals. The Jong et al composition is not lethal to the animal, while the present composition is. There is no disclosure or even suggestion for a composition that is lethal to the animal to which it is fed, nor to a composition including an insect food and an effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable) to control of insect populations, where the bacteria is present only in an effective amount with the remainder being the insect food and where the bacteria do not have to be viable.

Because Jong et al does not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, Jong et al does not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Claims 23-26 and 28-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kobayashi (JP 05247378 - CAPLUS Abstract), with evidence provided by the ATCC Catalogue of Bacteria and Bacteriophages (18th ed. 1992).

The Examiner contends as follows:

Kobayashi teaches a composition comprising *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized in the art as *Rhodobacter capsulatus* - i.e., *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*; however, *Rhodopseudomonas capsulatus*

has since been renamed *Rhodobacter capsulatus* - see, e.g., page 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*) as an active ingredient therein, whereby the composition further includes cellulose (a carbohydrate polymer) - see CAPLUS Abstract. Based upon the unclarity of claims 33-34 (including the lack of antecedent basis limitations discussed above), the composition, taught by Kobayashi reads upon these claims, as drafted. Please note that nothing would preclude the additional ingredient(s) disclosed by the cited reference from being used as "insect food."

Therefore, the reference is deemed to anticipate the instant claims above.

Applicants disagrees that Kobayashi discloses the composition of new claim 35-59. Kobayashi discloses coating for improving water quality. Again, the Kobayashi like the Jong et al composition is a bacteria culture composition - where the agents like carbohydrates and cellulose- are part of the food for the bacteria. Kobayashi does not disclose a composition of an insect food and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where the resulting composition is a lethal composition for the animal life for which it is intended. The Kobayashi is designed to improve water quality meaning that the bacteria must be viable. In the present invention, the bacteria do not have to be viable. The composition is lethal regardless of the state of the bacteria (alive, dead or extracted).

Because Kobayashi does not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, Kobayashi does not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Claims 23-26 and 28-34 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Life KK (JP 60027672 - **DWPI** Abstract), with evidence provided by the ATCC Catalogue Bacteria and Bacteriophages (18th ed., 1992).

The Examiner contends as follows:

Nippon Life KK teaches a composition comprising *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized in the art as *Rhodobacter capsulatus* -i.e., *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*, however, *Rhodopseudomonas capsulatus* has since been renamed *Rhodobacter capsulatus* - see, e.g., pages 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*) as an active ingredient therein, whereby the composition further includes various carbohydrate-containing ingredients including rice bran which would inherently comprise cellulosic material (e.g., cellulose - a carbohydrate polymer) - see **DWPI** Abstract. Based upon the unclarity of claims 33-

34 (including the lack of antecedent basis limitations discussed above), the composition taught by Nippon Life KK reads upon these claims, as drafted. Please note that nothing would preclude the additional ingredient(s) disclosed by the cited reference from being used as "insect food."

Therefore, the reference is deemed to anticipate the instant claims above.

Nippon Life KK discloses an aqueous fertilizer including food for the bacteria. Again, the new claims 35-59 do not relate to aqueous compositions, does not relate to composition designed to grow anything, but to compositions designed to kill things. The fertilizers of Nippon Life KK do not include an insect food and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death.

Because Nippon Life KK does not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, Nippon Life KK does not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Claims 23-26, 28-30, and 32-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated Matsuda (JP 05304959 - JPAB Abstract), with evidence provided by the ATCC Catalogue of Bacteria and Bacteriophages (18th ed 992).

The Examiner contends as follows:

Matsuda teaches a composition comprising *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized in the art as *Rhodobacter capsulatus* - i.e., *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*, however, *Rhodopseudomonas capsulatus* has since been renamed *Rhodobacter capsulatus* - see, e.g., pages 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*) in an amount of 10^6 - 10^{10} /g (which although very difficult to interpret due to the U.S.C. 112, second paragraph rejections above including those concerning lack of antecedent basis, appear to be within the approximately claimed amount range) as an active ingredient therein, whereby the composition further comprises a bacterial culture solution (which would inherently contain at least one carbohydrate therein) - see JPAB Abstract. Please note that nothing would preclude the additional ingredient(s) disclosed by the cited reference from being used as "insect food."

Therefore, the reference is deemed to anticipate the instant claims above.

Matsuda does not relate to a composition including an insect food and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable). Matsuda relates to an aqueous material contained in a bead for use in water treatment. Again, the composition only

contains incidental amount of carbohydrates and those are present for the bacteria to eat. This are not compositions lethal to the environment to which they are intended.

Because Matsuda does not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, Matsuda does not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Claims 23-26, 28-30, and 32-34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kobayashi et al (JP 09238681 - JPAB Abstract), with evidence provided by the ATCC Catalogue of Bacteria and Bacteriophages (18th ed 1992).

The Examiner contends as follows:

Kobayashi et al. teach a composition comprising *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized in the art as *Rhodobacter capsulatus* - i.e., *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*; however, *Rhodopseudomonas capsulatus* has since been renamed *Rhodobacter capsulatus* - see, e.g., pages 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*) as an active ingredient therein, whereby the composition further a seaweed polysaccharide (carbohydrate) - see JPAB Abstract. Based upon the unclarity of claims 33-34 (including the lack of antecedent basis limitations discussed above), the composition taught by Kobayashi et al. reads upon these claims, as drafted. Please note that nothing would preclude the additional ingredient(s) disclosed by the cited reference from being used as "insect food."

Therefore, the reference is deemed to anticipate the instant claims above.

Kobayashi et al also relates to compositions for water quality. The material is not lethal to its environment and does not result in the death of animals within the environment in which it is intended. Moreover, the carbohydrates used in the composition are either to form the material into a gel or are nutrients for the bacteria. New claims 35-59 relates to composition of an insect food (major component) and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death.

Because Kobayashi et al do not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, Kobayashi et al do not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Claims 23-26, 28-30, and 32-34 under 35 U.S.C. § 102(b) as being anticipated by the ATCC

Catalogue of Bacteria and Bacteriophages (18th ed. 1992).

The Examiner contends as follows:

The ATCC Catalogue teaches compositions comprising pure cultures (thus, apparently within the claimed amount ranges) of *Rhodopseudomonas capsulatus* (which, as evidenced by the ATCC Catalogue, is now well known and recognized in the art as *Rhodobacter capsulatus* *Rhodobacter capsulatus* was earlier known as *Rhodopseudomonas capsulatus*; however, *Rhodopseudomonas capsulatus* has since been renamed *Rhodobacter capsulatus* - see, e.g., pages 269 and 275 under the respective genus/species headings *Rhodobacter capsulatus* and *Rhodopseudomonas capsulatus*), whereby the composition further comprises a concentrated growth medium (which would inherently contain at least one carbohydrate therein) as well as double strength skim milk (which also inherently contains such as lactose)- see, e.g., pages vi, 269, 275, 542 and 543. Please note that nothing would preclude the additional ingredient(s) disclosed by used as "insect food".

Therefore, the reference is deemed to anticipate the instant claims above.

The ATCC Catalogue of Bacteria and Bacteriophages relates to culture media for growing the bacteria, not to compositions of killing insects. The amount of carbohydrate or cellulose is only sufficient as a nutrient for the bacteria in an aqueous form. The present invention as claimed in new claims 35-59 relates to a composition including an insect food (major component) and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death. Again, the composition of this invention is not designed to grow things, but to kill things.

Because ATCC Catalogue of Bacteria and Bacteriophages does not disclose a composition including an insect food and an insecticidal amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death, ATCC Catalogue of Bacteria and Bacteriophages does not anticipate nor render obvious the present invention of new claims 35-59. Applicants, therefore, respectfully request withdrawal of this section 102(b) rejection.

Rejections 35 U.S.C. § 103

Claims 23-26 and 27-34 stand rejections 35 U.S.C. § 103 (a) as being unpatentable over Jong et al. (KR 9411524 - DWPI Abstract), Kobayashi (JP 05247378-CAPLUS Abstract), Nippon Life KK (JP 60027672 - DWPI Abstract), Matsuda (JP -05304959 - JPAB Abstract), or Kobayashi et al. (JP 09238681 - JPAB Abstract), with evidence provided by the ATCC Catalogue of Bacteria and Bacteriophages (18th ed., 1992), or over the ATCC Catalogue of Bacteria and Bacteriophages (18th ed., 1992).

The Examiner contends as follows:

The references are relied upon for the reasons set forth above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition (such as any one of those disclosed by the cited references) comprising a result-effective amount of *Rhodobacter capsulatus* (*Rhodopseudomonas capsulatus*), especially since each of the cited references beneficially teach that this bacterial species is an active ingredient (and/or pure culture) therein. Accordingly, the adjustment of this particular conventional working conditions as well as other conventional working conditions (e.g. further including and/or substituting a commonly-employed, readily-available cellulosic carbohydrate source within such compositions), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over one or more of the cited references, especially in the absence of evidence to the contrary.

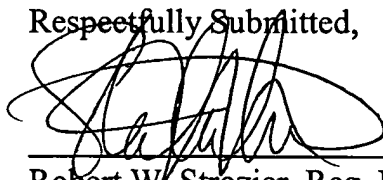
With respect to the U.S.C. 102 and 103 rejections above, it is noted that the cited references do each that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such unclosed use is inherent in the reference compositions. In order to be limiting, the intended use create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103 (MPEP 2112).

Applicants reassert all the points set forth above. None of the cited references, alone or in any combination, disclose, teach or suggest a composition including an insect food (major portion) and an insecticidal effective amount of *Rhodobacter capsulatus* bacteria (viable or non-viable), where ingestion results in insect death.

Because none of the cited references alone or in any combination relates to the claimed compositions or to any composition to relates to killing instead of growing, the cited reference along or in any combination cannot render obvious new claims 35-59. Applicant, therefore, respectfully requests withdrawal of this section 103 rejection.

The Commissioner is authorized to charge any additional claim fees to Deposit Account No. 501518.

Respectfully Submitted,



Robert W. Strozier, Reg. No. 34,024

Date: January 12, 2004